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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,000	05/16/2005	Masakazu Hatano	05318/HG	1933

1933 7590 09/28/2009

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EXAMINER	
HUANG, GIGI GEORGIANA	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
09/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,000	HATANO ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-13* is/are pending in the application.

4a) Of the above claim(s) *5-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/27/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

Status of Application

1. The response filed August 25, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claim 13 has been added.

2. Claims 1-2, 4-13 are pending in the case.

3. Claims 1-2, 4, 13 are present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

Information Disclosure Statement

6. The IDS filed 6/27/2005 as addressed Applicant is related to USP 4952581 and has been considered, and is enclosed in the action.

Claim Objections

7. Applicant is advised that should claim 1 be found allowable, claim 2 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof as there is no material differences in the composition components. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-2, 4, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azuma et al. (WO 00/09162).

It is noted that U.S. Pat. 6673812 will be used as the translation of the WIPO document. All references will be to the U.S. Pat.

Azuma et al. teaches a composition for glaucoma comprising a rho kinase inhibitor (Abstract). Azuma teaches the compositions can be in several forms including tablets, capsules, liquids, and drops. Azuma exemplifies the compositions including an eye drop comprising (R)- (+)-N- (1H-pyrrolo [2,3-b] pyridin- 4-yl)-4- (1-aminoethyl)benzamide (also known as Y-39983, Col. 22-Example 7, Claim 1, 8-9) and that the compound (labeled Compound D) had a long lasting affect (Col. 25.line 12-13). Azuma also teaches that beta blocker such as timolol are widely used for glaucoma as they lower intraocular pressure (Col. 1 line 39-43). It is noted that a recitation of intended use does not have patentable weight in a composition claim.

Azuma et al. do not expressly teach a composition with the combination of a rho-kinase inhibitor and a beta-blocker. Azuma does teach that combination therapy and that each of these compounds are useful for glaucoma.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine two drugs known to be effective for the same purpose as addressed by Azuma, and produce the instant invention.

As addressed in Azuma, beta-blockers are widely used for the treatment of glaucoma, and rho kinase inhibitors (exemplified by (R)- (+)-N- (1H-pyrrolo [2,3-b] pyridin- 4-yl)-4- (1-aminoethyl)benzamide) are also taught be useful for glaucoma, it is obvious to combine two drugs useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art and the use of additional actives (combination therapy) is taught by Azuma.

One of ordinary skill in the art would have been motivated to do this because it is desirable to have and produce a composition comprising many components which have desirable effects for the condition resulting in the additive effect of the ingredients for glaucoma. One would have been motivated to do this because it is desirable to produce a combination drug to be effective for as may conditions as possible as it would not only increase the drugs' versatility by being effective for the condition to be addressed, but also increase sales with nominal development.

Response to Arguments

9. Claims 1-2, 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azuma et al. (WO 00/09162).

Applicant's arguments filed 8/25/2009 have been fully considered but they are not persuasive. Applicant asserts that the combination of two known drugs for the same

purpose, one of skill in the art would have to have a reasonable expectation of success and that Azuma does not teach which type of glaucoma agent can be complimented and/or enhanced by a rho kinase inhibitor. Applicant also references the declaration by Hitano as evidence that Y-39983 is more preferable that other Rho kinase inhibitor with beta-blockers as HA1077. Applicant also argues that the effects of the Y-39983 and timolol are synergistic. This is not persuasive. First, the arguments are not commensurate in scope with the claims. The recitation of intended use does not have patentable weight in a composition claim. The recitation of intended motivation does not have patentable weight in a composition claim. Second, recitations of desired results do no materially change the components present in a composition claim. Third, as addressed in previous office actions, combination therapy is addressed by Azuma and well known in the art for glaucoma treatment. Fourth, as Azuma teaches combination therapy and that both beta-blockers which are widely used such as timolol, and Y-39983 are known for treating glaucoma, it is obvious to combine these components for the same purpose as combination therapy is know and taught with a reasonable expectation of success in affecting glaucoma. Fifth, Applicant refers to the comparative in the Hitano declaration as evidence that HA1077 and timolol are not synergistic and argues that the combination does not show persistence of action at 4 hours which is not persuasive as the combination of the HA1077 and timolol as addressed by Applicant did exhibit an additive effect 1-2 hours after instillation. Whereby there is an additive effect and supports the fact that there is a reasonable expectation of success to combine these two categories of agents. The arguments for persistence after 4 hours do not

have patentable weight in regards to composition claims. Lastly, as for the assertion that Y-39983 and timolol are synergistic, the figure presented does not show a synergism but an additive effect of the two components in combination particularly in hours 1-2, and as addressed above, the intended use of a composition does not have patentable weight in a composition claim.

Accordingly, the rejection is maintained.

Conclusion

10. Claims 1-2, 4, 13 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612